K010973

SEP 11 2001

510 (k) SUMMARY

SUBMITTED BY:

Bruce A. MacFarlane, Ph.D.
Hypoguard USA, Inc.
5182 West 76th Street
Minneapolis, MN 55439
952-646-3188
March 30, 2001

NAMES OF DEVICES:

Trade Names: DiaScreen®50 Urine Chemistry Analyzer; DiaScreen® Reagent Strips for Urinalysis

Common Names/Descriptions: Automated Urinalysis System; Urinalysis Test Strips

Classification Names: Automated Urinalysis System; Test strip reagents define classification: specific gravity, pH, blood, leukocytes, nitrite, protein, bilirubin, ketone (acetoacetic acid), glucose, and urobilinogen

PREDICATE DEVICE: Bayer Clinitek 50 Urine Chemistry Analyzer

DEVICE DESCRIPTION: Automated Urinalysis System

The DiaScreen®50 Urine Chemistry Analyzer is a simple-to-operate, portable, line-powered bench top instrument that reads the color changes of DiaScreen® Reagent Strips for Urinalysis. Up to 10 analytes can be read from a single test strip.

The user operates the Analyzer using the "Up" and "Down" buttons to scroll through a software-driven, function menu displayed on the Analyzer's Liquid Crystal Display (LCD). The operator presses the "Analyzer/Enter" button to start the analysis or to select menu options. The "Feed" button is used to automatically feed the paper roll used for hardcopy printout.

DiaScreen® Reagent Strips for Urinalysis are plastic strips coated with one or more dry reagents. Each reagent is specific for a particular analyte. Reagent areas are spaced along the test strip, with a physical gap between reagent areas. Several product configurations are commercially available, detecting one or more of the following analytes: specific gravity, pH, blood, leukocytes, nitrite, protein, bilirubin, ketone (acetoacetic acid), glucose, and urobilinogen. The dry reagents change color in reaction to the presence, and concentration, of their associated analyte. The strips may

be read visually against a color chart or may be read using the DiaScreen®50 Urine Chemistry Analyzer.

Each test pad is read photometrically within a total incubation time of approximately 70 seconds. In strongly alkaline urine samples, the Analyzer automatically corrects the result of the specific gravity test.

The test strips are included in this submission solely due to modification of Intended Use to include the option of reading strips with the Analyzer.

INTENDED USE:

DiaScreen®50 Urine Chemistry Analyzer:

The DiaScreen®50 Urine Chemistry Analyzer is an automated urinalysis instrument intended for reading Hypoguard DiaScreen® Reagent Strips for Urinalysis. The tests provided on DiaScreen® Reagent Strips are considered routine urinalysis.

DiaScreen® Reagent Strip for Urinalysis:

DiaScreen® Reagent Strips for Urinalysis are dip-and-read test strips intended for use as an *in vitro* diagnostic aid using urine specimens. DiaScreen Reagent Strips provide qualitative and semiquantitative tests for specific gravity, pH, blood, leukocytes, nitrite, protein, bilirubin, ketone (acetoacetic acid), glucose, and urobilinogen by visual comparison to a color chart or by use of the DiaScreen®50 Urine Chemistry Analyzer. The tests provided are considered routine urinalysis.

TECHNOLOGICAL CHARACTERISTICS:

The DiaScreen 50 Urine Chemistry Analyzer is a reflectance photometer designed to read and interpret the results of the DiaScreen Reagent Strips. The instrument reads the strips, stores the results in memory, and prints a hardcopy from its built-in printer. Results are also displayed on the LCD screen during data processing. To operate, a test strip is dipped in urine and placed on the test strip tray. The user then presses the Analyze/Enter button which causes the tray to be retracted inside the instrument, placing the test strip reagent pads under the reading head.

The reading head contains six light-emitting diodes (LEDs) as illumination sources. The LEDs emit light at one of three (3) defined wavelengths onto the surface of the reagent test pads on the strip. The light hitting each individual test pad is reflected proportional to the color produced on the test pad and is detected by a phototransistor positioned directly above the test pad. Each test pad has a dedicated phototransistor. The phototransistor sends an analog electrical signal to an Analog/Digital converter that generates a digital signal. A microprocessor converts the digital signal into a relative reflectance value by referring to a calibration standard. The three pairs of LEDs calibrate the instrument using a white spot on the end of the test strip tray. Specific

gravity results are corrected for pH in strongly alkaline urine. Finally, the system compares the reflectance value with the defined range limits (=reflectance values which are programmed into the Analyzer for each parameter) and displays a semi-quantitative result which is printed out. Each test pad is read photometrically within a total incubation time of approximately 70 seconds. In strongly alkaline urine samples, the Analyzer automatically corrects the result of the specific gravity test.

The DiaScreen 50 Urine Chemistry Analyzer has the same fundamental technological characteristics as its predicate device.

NON-CLINICAL TESTING:

In-house correlation and precision testing was conducted and showed performance to be substantially equivalent to that of the predicate.

CLINICAL TESTING:

Correlation and precision testing was conducted at 4 clinical sites. Results indicated performance was substantially equivalent to that of the predicate.

CONCLUSIONS FROM TESTING:

Testing demonstrated that performance of the new urine chemistry analyzer system was substantially equivalent to that of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 2001

Bruce A. MacFarlane, Ph.D.
Vice President, Regulatory Affairs and Quality Systems
Hypoguard USA, Inc
5182 West 76th Street
Minneapolis, MN 55439

Re: k010973
Trade/Device Name: DiaScreen®50 Urine Chemistry Analyzer
DiaScreen® Reagent Strip for Urinalysis
Regulation Number: 21 CFR 862.6550
21 CFR 862.1340
21 CFR 862.2900
Regulation Name: Occult Blood, Urine Glucose, Automated Urinalysis System
Regulatory Class: Class II
Product Code: JIO; JIL; KQO
Dated: July 25, 2001
Received: July 26, 2001

Dear Dr. MacFarlane:

This correction letter changes the product code from KQR, (which was a typographical error) to KQO. The other product code change is from KHE to JIO.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K010973

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DiaScreen® Reagent Strip for Urinalysis

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ PRESCRIPTION USE

Kevin Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010973

(Optional Format 3-10-98)